

HUMAN RESEARCH ETHICS COMMITTEE
TEMPLATE ANNUAL REPORT FORM

Only typewritten reports will be accepted.

HREC Approved Project No:

Project Title:

Protocol Number:

Principal Investigator:

Address:

All current co-investigators.

If any co-investigators have left the project during the year, please list their names and date of departure from the project.

THIS PROJECTS HAS (please tick appropriate box)

BEEN ABANDONED
Please state reason

NOT COMMENCED*
Expected starting date

COMMENCED }
} *Complete page 2 of report*

COMPLETED/TERMINATED }

A DRUG COMPONENT *Complete Drug Trial Addendum*

* Note if a study has not commenced within 12 months of the ethics approval date, and no approval extension has been previously arranged, the approval lapses. The study will then have to be resubmitted before it can commence.

WAS FUNDING SOUGHT FROM AN AGENCY OR FOUNDATION?

If Yes What Agency
Was the application successful Yes No

If No Please state what source of funding is being used for this project

HREC Approved Project No.

1. Date of ethics approval from Austin Health./...../.....

2. Date project commenced at Austin Health./...../.....

3. Date original ethics approval lapses/lapsed./...../.....

4. Date when you expect to complete the project?/...../.....

5. Has an extension of ethical approval been granted?

Yes No Not requested

6.a) If yes, what is the date the extension of approval lapses?/...../.....

6. b) If no, and your expected completion date falls beyond the period of ethical approval, please write to the HREC requesting an extension of approval and providing justification for this extension.

7. Have any unanticipated ethical issues emerged during the course of the project?

Yes No *If yes, please provide details*

8. Is the project being conducted in compliance with the protocol?

Yes No *If no, please provide details*

9. Is the project being conducted in compliance with any conditions of approval?

Yes No *If no, please provide details*

10. Have there been, or will there be, any significant changes in procedure or direction of the project, or in the source, or manner of recruitment, number of subjects etc?

Yes No *If yes, please provide details*

11. Are the records and data collected during the conduct of the study stored and maintained in a secure location?

Yes No *Please provide details*

12. Please give a brief summary of the results of the research to date

13. What anticipated benefits have been involved?

14. Please list any published papers, or presentations relating to this study

15. Please state the version number, date and name of all the current Participant Information and Consent Forms used in this study

16. Are records being maintained according to the National Statement on Ethical Conduct in Human Research (2007)?

Yes **No**

If no please explain-

I confirm that this project is being conducted as originally approved by the Austin Health Human Research Ethics Committee, subject to any changes as indicated above and is conducted in compliance with the NHMRC/ARC/AVCC National Statement on Ethical Conduct in Human Research (2007).

.....

Principal Investigator

...../...../.....

Date

DRUG TRIAL ADDENDUM

Numbers of patients

- expected on trial
- screened
- entered / randomised
- currently on treatment
- completed treatment
- who dropped out without completing treatment (and reason for dropping out)
- on follow-up
- completed follow-up
- Is the trial recruitment open? If no, when did it close

Serious Adverse Events

..... Number of internal SAE reports

Dates reported to HREC

.....

.....

.....

.....

Protocol Violations

List of protocol violations (include those already reported to HREC marked with an *).

.....

.....

.....

.....

.....